

CLAIMS:

1. A process of forming a pharmaceutical aerosol formulation, said process comprising:

5 subjecting particulate salbutamol sulphate to a temperature of between about 0°C and about 100°C with a relative humidity of between about 20% to about 90% to form annealed particulate salbutamol sulphate; and
combining the annealed salbutamol sulphate with a propellant comprising 1, 1, 1, 2-tetrafluoroethane to form a pharmaceutical aerosol formulation.

10

2. The process according to Claim 1, wherein said step of subjecting particulate salbutamol sulphate to a temperature of between about 0°C and about 100°C with a relative humidity of between about 20% to about 90% comprises subjecting particulate salbutamol sulphate to a temperature of between about 10°C and about 50°C with a relative humidity of between about 55% to about 65%.

15

3. The process according to Claim 1, wherein said step of subjecting particulate salbutamol sulphate to a temperature of between about 0°C and about 100°C with a relative humidity of between about 20% to about 90% comprises subjecting particulate salbutamol sulphate to a temperature of between about 20°C and about 30°C with a relative humidity of about 60%.

20

4. The process according to Claim 1, wherein the annealed particulate salbutamol sulphate is present in the pharmaceutical aerosol formulation in an amount from about 0.01 to about 1% w/w.

25

5. The process according to Claim 1, wherein the annealed

particulate salbutamol sulphate is present in the pharmaceutical aerosol formulation an amount ranging from about 0.05 to about 0.2% w/w.

6. The process according to Claim 1, the pharmaceutical
5 aerosol formulation consisting essentially of the annealed particulate salbutamol sulphate and 1, 1, 1, 2-tetrafluoroethane as propellant.

7. The process according to Claim 1, wherein the annealed
10 particulate salbutamol sulphate is substantially thermally inactive as measured by microcalorimetry at about 25°C and between about 30% to about 90% relative humidity.

8. The process according to Claim 7, wherein the annealed particulate
15 salbutamol sulphate is micronized and includes a recrystallized outer layer.

9. The process according to Claim 7, where the annealed
particulate salbutamol sulphate has a water content of less than about 0.4% by
weight.

20
10. The process according to Claim 9, wherein said
annealed particulate salbutamol sulphate has a water content of less than about
0.35% by weight.

25
11. A process of forming a pharmaceutical aerosol formulation,
said process comprising:
subjecting particulate salbutamol sulphate to elevated temperatures under
vacuum to form annealed particulate salbutamol sulphate; and

combining the annealed salbutamol sulphate with a propellant comprising 1, 1, 1, 2-tetrafluoroethane to form a pharmaceutical aerosol formulation.

12. The process according to Claim 11, wherein said step of
5 subjecting particulate salbutamol sulphate to elevated temperatures under vacuum to form annealed particulate salbutamol sulphate comprises subjecting particulate salbutamol sulphate to a temperature of from about 40°C to about 100°C.

13. The process according to Claim 11, wherein said step of
10 subjecting particulate salbutamol sulphate to elevated temperatures under vacuum to form annealed particulate salbutamol sulphate comprises subjecting particulate salbutamol sulphate to a temperature greater than about 60°C.

14. The process according to Claim 11, wherein the
15 annealed particulate salbutamol sulphate is present in the pharmaceutical aerosol formulation in an amount from about 0.01 to about 1% w/w.

15. The process according to Claim 11, wherein the annealed
particulate salbutamol sulphate is present in the pharmaceutical aerosol formulation
20 an amount ranging from about 0.05 to about 0.2% w/w.

16. The process according to Claim 11, the pharmaceutical
aerosol formulation consisting essentially of the annealed particulate salbutamol
sulphate and 1, 1, 1, 2-tetrafluoroethane as propellant.

17. The process according to Claim 11, wherein the annealed

particulate salbutamol sulphate is substantially thermally inactive as measured by microcalorimetry at about 25°C and between about 30% to about 90% relative humidity.

5 18. The process according to Claim 17, wherein the annealed particulate salbutamol sulphate is micronized and includes a recrystallized outer layer.

10 19. The process according to Claim 17, where the annealed particulate salbutamol sulphate has a water content of less than about 0.4% by weight.

20. The process according to Claim 20, wherein said annealed particulate salbutamol sulphate has a water content of less than about 0.35% by weight.